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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,482	11/19/2003	Naveen Arora	2761-0169P	3751

2292 7590 08/05/2005

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,482	ARORA ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,21 and 26-34* is/are pending in the application.

4a) Of the above claim(s) *26-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/2/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. This Office action is responsive to Applicant's amendment and response filed May 2, 2005. Claims 1, 3, 5-6 and 21 have been amended. Claims 9-20 and 22-26 have been cancelled.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

3. ***Election/Restriction***

Newly submitted claims 26-34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Newly submitted claims 26-34 are drawn to a method of inhibiting anthrax toxin and are distinct from examined claims 1-8 and 21 which are drawn to an isolated protein, since the isolated is a product, where as claims newly submitted claims 26-34 are drawn to methods of using that product. Originally presented claims 1-8 and 21 and newly submitted claims 26-34 are related as product and process of using. In the instant case, the invention as set forth in the originally presented claims is a product (protein) which can be used to make antibodies which a different use from the use set forth in newly submitted claims 26-34. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-

34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Objections/Rejection Maintained

4. In view of Applicant's amendment and response the following objections/rejections are withdrawn:

a) objection to claims 1-8 and 21, page 2, paragraph 2.
b) objection the claim 21, page 2, paragraph 3.
c) rejection of claims 1 and 3-8 under 35 U.S.C. 101, page 3, paragraph 4.

Rejections Maintained

5. The rejection of claims 1-8 and 21 under 35 U.S.C. 112, first paragraph is maintained for the reasons set forth on pages 3-4, paragraph 5 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention.

The claims are directed to a novel protein capable of inhibiting anthrax toxin activity. Dependent claims 2 and 21 recite "... wherein the protein is isolated from pollen grains of a grass of a genus selected from the group consisting of *Imperata,* a genus related to *Imperata*, *Lolium*, a genus related to *Lolcium*, *Phleum*, a genus related to *Phleum*, *Cynodon* and a genus related to *Cynodon*" and "...wherein the grass is selected from the group consisting of *Imperata cylindrica, Lolium perenne, Phleum pretense* and *Cynodon datylon*". Therefore, the claims encompass a genus of 67 kDa proteins.

The specification only provides written description for the 67 kDa protein isolated from *Imperata cylindrica.* There is no disclosure that the claimed protein was isolated from a grass other than *Imperata cylindrica.* The instant specification does not describe a 67 kDa protein isolated from pollen grains of a grass of a genus selected from the group consisting of *Imperata,* a genus related to *Imperata*, *Lolium*, a genus related to *Lolcium*, *Phleum*, a genus related to *Phleum*, *Cynodon* and a genus related to

Cynodon". The specification also fails to provide adequate written description for claimed protein isolated from *Lolium perenne, Phleum pretense* or *Cynodon datylon.*

Bijli et al (*Clin. Exp. Allergy, January 2003, 33:65-71)* teach a 67kDa protein purified from *Imperata cylindrica* (page 65). Verma et al *(International Archives of Allergy and Immunology, 2000, 122:251-256)* teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 252). Therefore, one of skill in the art would not conclude that the claimed novel 67-kda protein could be isolated from a grass other than *Imperata cylindrica*. One skilled in the art would not conclude that Applicant was not in possession of the claimed genus of 67 kDa proteins at the time of filing. Therefore, Applicant has not met the written description requirements as set forth in 35 U.S.C. 112, first paragraph.

Applicant urges that the instant specification very well describes the invention in generic form. Applicant urges that the structural and functional characteristics of the protein are set forth in detail. Applicant urges that the Examiner on one hand says that the generic characteristics of the claimed invention are not sufficient to clearly distinguish what the invention is from other proteins and then at the same time asset that such generic characteristics are sufficient to establish that the protein so described inherently possesses certain biological activities.

Applicant's arguments filed May 5, 2005 have been fully considered but they are not persuasive. It must be remembered that this rejection is made under 35 U.S.C. 112, first paragraph and is set forth as a written description rejection. It must be also be remembered that 35 U.S.C. 112, first paragraph (written description) requires that Applicants were in possession of the claimed invention at the time of filing. The rejection under 112 first paragraph was set forth because according to the instant disclosure, Applicants were only in possession of a 67 kDa protein that was isolated from *Imperata cylindrical* and not from that other genus such as *Lolium*, *Phleum* and Cynodon. It is established in art that the claimed 67 Kda protein can be isolated from

Imperata cylindrical. Nowhere in the instant specification has Applicants disclosed a 67 kDA protein isolated from other genus such as *Lolium*, *Phleum* and *Cynodon* as claimed by Applicants. Therefore, the specification also fails to provide adequate written description for claimed protein isolated from *Lolium perenne, Phleum pretense* or *Cynodon datylon.* Therefore, one skilled in the art would not conclude that Applicants were in possession of 67 kDa proteins isolated from *Lolium perenne, Phleum pretense* or *Cynodon datylon* at the time of filing.

To address Applicant's comments regarding the invention not being adequately described on one hand and then on the other hand the generic characteristics are sufficient to establish that the protein so described inherently possesses certain biological activities, it should be noted that under 35 U.S.C. 112, first paragraph (written description) the requirement is that Applicant is in possession of the claimed invention at the time of filing and the requirement under 35 U.S.C. 102 requires that the same invention is taught in the prior art. It should be noted that each invention must be individually examined under each statue and the examination of one statue is independent of the examination of another statue.

For the reasons set forth above, this rejection is maintained.

6. The rejection of claims 1-8 and 21 under 35 U.S.C. 112, first paragraph is maintained for the reasons set forth on pages 5-8, paragraph 6 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a novel protein capable of inhibiting anthrax toxin activity.

The specification teaches that the protein of the invention can inhibit activity of anthrax toxin (page 2). The specification teaches that the protein has the utility for developing a therapeutic agent that can reduce the toxic effects once the disease has set in (page 2). Therefore the instant specification contemplates the use of the claimed 67 kDa protein to treat anthrax *in vivo*. The specification only discloses inhibition studies *in vitro* using claimed 67 kDa protein incubated with J774A.1 (eukaryotic) cells (pages 7-8). The specification has failed to correlate *in vivo* treatment of anthrax using the claimed protein and the *in vitro* treatment of anthrax using the claimed protein. The specification teaches that the novel protein for inhibition of activity of anthrax and the purified protein has the ability or reduce the toxic effects of anthrax (page 2). What toxic effects are reduce? The toxic effects of PA or LF or both or other toxins? What constitutes a reduction? The specification and claims teach that the claimed 67-kDa protein has IgE binding properties. The specification further teaches that in *in vitro* assays using the claimed protein and *Imperata cylindrica* (Ic) hypersensitive individual's sera, 10 out of 12 sera demonstrated it to be a major allergen (page 6 and Figure 2). Example 7 of the instant specification teaches that the 67 kDa protein was "preincubated" with the J774A.1 cell line in an *in vitro* assay. Therefore, a "preincubation" of the protein with the cells is required. How does this correlate with administering the 67 kDa protein *in vivo*? Will the protein effective *in vivo* if preincubation is not possible? How is the preincubation requirement met *in vivo*? Does the 67 kDa protein reach the reach the target site to inhibit the PA and LF antigens? Verma et al *(International Archives of Allergy and Immunology, 2000, 122:251-256)* teach that grass pollen allergens have been implicated in the induction of type I allergic disorders in atopic individuals (page 251). Verma et al teach that the 67 kDa protein isolated from *Imperata cylindrica* Pollen Extract showed high IgE binding in ELISA and reacted with 80% of the patients' sera and suggest that the 67 kDa protein may be a new allergen (page 255). Vieths et al (*Ann N.Y. Acad. Sci., 964:47-68, 2002)* teach that pollen-allergic patients frequently present allergic symptoms after ingestion of several kinds of plant-derived food (see the Abstract). Vieths et al teach that approximately 15-

20% of the population in developed countries are allergic to pollen and 50-93% of birch pollen-allergic patients have IgE mediated reactions to pollen related foods (page 48). Vieths et al teach that at the molecular level, observations are based on the cross-reactions of human IgE antibodies which are directed against pollen allergens with homologous allergens in plant food (page 48). How would the claimed 67 kDa protein react when administered *in vivo* to patients that produce high levels of IgE neutralizing antibodies due to allergic reactions? Zhao et al *(Human Antibodies, 2003; 12(4):129-35)* teach that neutralizing monoclonal antibodies can block the action of anthrax toxin lethal toxin factor formation (see the Abstract). If neutralizing antibodies are to LF are present, how does the effected the claimed protein when administered *in vivo*?

One of skill in the art could not have reason to doubt the assertion that the claimed 67 kDa protein would be effective in inhibiting anthrax in vivo based on the teachings of the cited art and the absence of evidence in the instant disclosure to correlate inhibition of the anthrax toxins with in vivo administration of the claimed protein.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to using the claimed protein to inhibit the anthrax toxin *in vivo* 3) there are no working examples which suggest the desired results of a successful use of the claimed protein and 4) the relative skill of those in the art is commonly recognized as quite high (post - doctoral level).

In view of all of the above, it is determined that the specification has not provided guidance that would enable one of skill in the art to be able to use the claimed invention commensurate with the claims. One of skill in the art would require undue experimentation to determine whether the claimed 67 kDa protein can be used to treat or inhibit anthrax toxins *in vivo.*

Applicant urges that the Examiner is trying to restrict Applicants to only the scope of the working example provided. Applicant urges that the question of enablement is one of whether or not undue experimentation is required to practice the invention throughout its scope. Applicant urges that the instant specification provides more than adequate guidance for making and using the invention as presently claimed. Applicant

urges that the specification describes by genus and species that can be used as starting materials for obtaining the protein to be used in the invention. Applicant urges that the plants are demonstrated to be immunologically cross-reactive. Applicant refers to Figure 3 (a) of the instant specification. Applicant urges that the instant specification provides a detailed protocol for extracting the effective protein and also provides detailed biochemical tests for the activities the protein is to exhibit. Applicant refers to Examples 2-4 of the instant specification. Applicant asserts that guidance is provided in the instant specification so that the skilled artisan can make and use the claimed invention. Applicant urges that the Examiner has relied upon unpredictability in the art to make her case. Applicant urges that no undue experimentation is required to practice the instant invention.

Applicant's arguments filed May 5, 2005 have been fully considered but they are not persuasive. This rejection is set forth because the instant disclosure teaches that the protein of the invention can inhibit activity of anthrax toxin. The instant specification has failed to correlate *in vivo* treatment of anthrax using the claimed protein and the *in vitro* treatment using the claimed protein. Previously cited references have taught that the 67 kDa protein isolated from *Imperata cylindrical* show high IgE binding and at the molecular level, observations are based on the cross-reactions of human IgE antibodies which are directed against pollen allergens with homologous allergens in plant food. Therefore, how would the claimed 67 kDA protein react when administered *in vivo* to patients that produce high levels of IgE neutralizing antibodies due to allergic reactions? It should be remembered that the instant specification contemplates the use of the

claimed 67 kDa protein to treat anthrax *in vivo* and within this scope patients with high levels are included. One of skill in the art would not conclude that the claimed 67 kDa protein would be effective in inhibiting anthrax *in vivo* based on the teachings of the cited art and the absence of evidence in the instant disclosure to correlate inhibition of the anthrax toxins with *in vivo* administration of the claimed protein.

To address Applicant's comment regarding Examples 2- 7of the instant specification, examples 2-4 merely showed that the claimed protein can be isolated and purified from *Imperata cylindrical* . Example 5 merely describes the SDS-PAGE and immunoblotting of the claimed protein. Example 6 merely demonstrates *in vitro* activity of the claimed protein. Example 7 of the instant specification teaches that the 67 kDa protein was "preincubated" with the J774A.1 cell line in an *in vitro* assay. Therefore, a "preincubation" of the protein with the cells is required. How does this correlate with administering the 67 kDa protein *in vivo*? Will the protein be effective *in vivo* if preincubation is not possible? How is the preincubation requirement met *in vivo*? Does the 67 kDa protein reach the target site to inhibit the PA and LF antigens?

To address Applicant's comments regarding cross-reactivity and Figure 3(a) of the instant specification, figure 3(a) shows cross-reactivity of 67 kDa hypersensitive sera to *Imperata cylindria, Cynodon dactylon, Lolium perenne and Phleum prastense*. As stated above, previously cited references have taught that the 67 kDa protein isolated from *Imperata cylindrical* show high IgE binding and at the molecular level, observations are based on the cross-reactions of human IgE antibodies which are directed against pollen allergens with homologous allergens in plant food. Therefore,

how would the claimed 67 kDA protein react when administered *in vivo* to patients that produce high levels of IgE neutralizing antibodies due to allergic reactions? It must be remembered that this rejection is made under 35 U.S.C. 112, first paragraph (enablement) which requires that Applicant teach how to make and use the claimed invention. Applicant has failed to show how the claimed protein can be used to treat anthrax *in vivo* which is contemplated by the instant disclosure. Thus, Applicant has failed to teach how to make and use the claimed invention as required under 35 U.S.C. 112, first paragraph. Therefore, the rejection is maintained.

7. The rejection of claims 1-8 and 21 under 35 U.S.C. 102(a) as anticipated by Bijli et al *(Clin. Exp. Allergy, January 2003)* is maintained for the reasons set forth on pages 5-8, paragraph 6 of the previous Office Action.

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* (page 65). Bijli et al teach a protein that is stable at room temperature (see Abstract). Bijli et al teach a 67kDa protein binds IgE (page 68). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner", "is devoid of any carbohydrate moiety", "wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that it is not clear as to whether the data used in the prior art reference is obtained from an "isolated protein". Applicant urges that Bijli et al do not disclose any protein that may be contacted with the toxin of *Bacillus anthracis* so as to inhibit the toxin activity of anthrax.

Applicant's arguments filed May 5, 2005 have been fully considered but they are not persuasive. Bijli et al teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract and Figure 2). Applicant has provided no side-by-side comparison to show that the claimed protein differs from that of the prior art reference. Since the protein of the prior art and the claimed protein are the same the protein of the prior art would necessarily possess all of the same biological activities as the claimed protein. Bijli et al, 2003 anticipate the claimed invention.

8. The rejection of claims 1-8 and 21 under 35 U.S.C. 102(b) as anticipated by Bijli et al *(Journal of Immunological Methods 260 (Feb. 2002, 91-96)* is maintained for the reasons set forth on pages 9-10, paragraph 8 of the previous Office Action.

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 93, Figures 1 (a)-(c)). Bijli et al teach a protein that is stable at room temperature (page 92). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner" and "is devoid of any carbohydrate moiety", wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" "wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that it is not clear as to whether the data used in the prior art reference is obtained from an "isolated protein". Applicant urges that Bijli et al do not disclose any protein that may be contacted with the toxin of *Bacillus anthracis* so as to inhibit the toxin activity of anthrax.

Applicant's arguments filed May 5, 2005 have been fully considered but they are not persuasive. Bijli et al teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract, pages 92-93 and Figure 1). Applicant has provided no side-by-side comparison to show that the claimed protein differs from that of the prior art reference. Since the protein of the prior art and the claimed protein are the same the protein of the prior art would necessarily possess all of the same biological activities as the claimed protein. Bijli et al, 2002 anticipate the claimed invention.

9. The rejection of claims 1-8 and 21 under 35 U.S.C. 102(b) as anticipated by Verma et al *(International Archives of Allergy and Immunology, 200, 122:251-256)* is maintained for the reasons set forth on pages 9-10, paragraph 8 of the previous Office Action.

The rejection was on the grounds that Verma et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 252). Bijli et al teach a protein that is stable at room temperature (page 252). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner" and "is devoid of any carbohydrate moiety", wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that it is not clear as to whether the data used in the prior art reference is obtained from an "isolated protein". Applicant urges that Verma et al do not disclose any protein that may be contacted with the toxin of *Bacillus anthracis* so as to inhibit the toxin activity of anthrax.

Applicant's arguments filed May 5, 2005 have been fully considered but they are not persuasive. Verma et al teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the

Abstract, page 252 and Figure 4). Verma et al also teach that the 67 kDa protein was purified using various chromatography methods (page 252). Applicant has provided no side-by-side comparison to show that the claimed protein differs from that of the prior art reference. Since the protein of the prior art and the claimed protein are the same the protein of the prior art would necessarily possess all of the same biological activities as the claimed protein. Verma et al anticipate the claimed invention.

Status of Claims

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
August 3, 2005

NITA MINNIFIELD
PRIMARY EXAMINER
8/3/05